

SPECIFICATION

Please amend the specification as follows. Applicant attests there is no new material presented in the specification as proposed below.

Examiner noted that the second paragraph of the disclosure (Cross Reference to Related Applications) "is replete with errors...multiple words are missing letters." Believing this to be a computer anomaly, applicant has deleted that section and replaced it with a larger font, below (application page 1, first paragraph through page 2, second paragraph).

Cross References to Related Applications

~~*The present patent application adds another very useful but unobvious configuration for active insulation of the disposable patient intravenous line of my US Patent Number*~~

~~6,608,968 B2, issued August 19, 2003. Because it is new material it is presently submitted as an independent new patent application rather than as a reissue application.~~

~~The improvements of this invention are applicable to other blood warmers not employing vapor condensation heating which use other means to achieve in-line warming of blood or intravenous fluids.~~

~~The present invention relates to delivering warm fluid to a patient at low flow rates, all the way down to essentially zero flow rate, providing fluid at 37 degrees C leaving the patient line i.v. tubing 6 ft from the blood warmer outlet. When used with the invention of my previous patent this results in over-all warmer performance which delivers fluid warmed to at least 35C from zero to 600 ml/min when entering fluid is 10C.~~

~~Thus the present invention describes a convenient, low-cost, disposable patient intravenous line using passive insulation and active warming applicable to any in-line blood/fluid warming device.~~

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Thus the present invention describes a convenient, low-cost, disposable patient intravenous line using passive insulation and active warming applicable to any in-line blood/fluid warming device.

Please amend "Brief Description of the Drawings" (application near bottom page 6) as indicated below. Applicant attests there is no new material in the proposed amendment.

Brief Description of the Drawings

Fig. 1 is a drawing of the air insulated flexible tube patient line with internal disposable heater

Fig. 1A is a perspective drawing of the disposable internal electrical resistance heater cable connector wires penetrating the outer wall of the Disposable air insulated patient intravenous line at a distance from the inlet of from one tenth to one half its length, with part of its outer wall removed to show their electrical and mechanical connections to the disposable internal electrical resistance heater segment

Fig. 1B is a perspective drawing of the air insulated patient line with internal disposable heater at the warm blood/fluid outlet to patient connection but with the outlet fitment removed showing that the disposable internal electrical resistance heater segments extend all the way to the warm blood/fluid outlet to the patient

connection and their electrical and mechanical connection via the disposable
internal electrical resistance heater segment connector wire

Fig. 2 is a an enlarged cross-sectional view of air insulated patient line with internal disposable heater on line 2-2 of Fig. 1 and in the direction of the arrows

Fig. 3 is a perspective drawing of electrical resistance heater segments made by
winding wire in a tightly spaced helical form on elongated plastic rods or tubes
about 0.1 inches in diameter

Fig. 4 is a perspective drawing of electrical resistance heater segments made by
winding wire in a tightly spaced quasi helical form on elongated, flexible strip
shaped insulators about 0.03 inch thick and about 0.10 to 0.25 inch wide

Please amend the section "Reference Numerals" (top of page 7 of application) as shown below. Applicant attests there is no new material in the proposed amendment,

Reference Numerals

- 1 Passively, still-air insulated and electrically actively warmed disposable outlet patient flow line system for in-line blood/fluid warmers
- 10 ~~Disposable air insulated patient intravenous line~~ Flexible tube flow line made of polyvinyl chloride or other resinous material
- 12 Warm blood/fluid inlet from in-line warming device
- 14 Warm blood/fluid outlet to patient connection
- 16 Disposable internal electrical resistance heater segment
- 18 Disposable internal electrical resistance heater cable
- 20 Disposable internal heater connector plug
- 21 Temperature sensor cable
- 22 Disposable internal electrical resistance heater cable connector wire
- 23 Electrical and mechanical connection of internal electrical resistance heater cable connector wire to internal electrical resistance heater segment
- 24 Disposable internal electrical resistance heater segment connector wire
- 25 Electrical and mechanical connections of internal electrical resistance heater segment connector wire to internal electrical resistance heater segments
- 26 Disposable electrical resistance heater segment made by winding wire in a

tightly spaced helical form on an elongated plastic rod or tube about 0.1 inches in diameter

28 Disposable internal electrical resistance heater segment in the form of wire wound in a tightly spaced quasi helical form on elongated, flexible strip shaped insulators about 0.03 inch thick and about 0.10 to 0.25 inch wide

30 Temperature sensor if employed

Please amend the specification sections "Preferred Embodiment—Description" and "Preferred Embodiment—Operation" as shown below. These sections begin on the second half of page 7 of the application and continue onto page 8. Applicant attests there is no new material in the proposed amendment.

PREFERRED EMBODIMENT -- DESCRIPTION

~~A flexible disposable internal electrical resistance heater 16, such as a wire or metal ribbon is manufactured as part of the disposable air insulated patient~~

~~intravenous line 10, and located in the annular air space as shown in Fig. 2. The heaters 16 are connected to disposable internal electrical resistance heater cable 18 and to each other at the distal end of the air insulated patient line forming a series resistance circuit. As shown in Fig. 1, heater cable 18 is then connected to a temperature controller in the blood warmer using disposable internal heater connector 20. Temperature control may be achieved using the heater 16 as a sensor when made of a metal with a high TCR (temperature coefficient of resistance) or by a separate sensor such as a thermistor.~~

Geometry of Tubing

Fig.1 is an over-all view of the current invention 1, a passively, still-air insulated and electrically actively warmed disposable outlet patient flow line system for in-line blood/fluid warmers mainly comprising a flexible tube flow line made of polyvinyl chloride or other resinous material 10, having a central blood-carrying tube about 0.12 inch inside diameter and a wall thickness of about 0.04 inch, and is supported inside a larger tube which is co-extruded with said central tube and has an outside diameter of about 0.37 inch and a wall thickness of about 0.04 inch, said central and outer tubes being interconnected by co-extruded webs about 0.04 inch thick which appear in cross section as a planar diametrical web across the entire cross section with the exception of said central tube's lumen, wherein an annular space between said central and outer tubes is filled

with heat insulative still air. The geometry of the flexible tube flow line is clearly shown in Fig. 2. Warm blood/fluid inlet 12 is a fitment adapted to connect to the warm blood outlet of an in-line blood warmer apparatus. Warm blood/fluid outlet 14 is a fitment adapted to a patient intravenous site.

Electrical Components

Two flexible elongated disposable internal electrical resistance heater segments 16, such as a wire or metal ribbon are manufactured as part of the disposable air insulated patient intravenous line 10, and located in the annular air space as shown in Fig. 2. The two flexible elongated disposable internal electrical resistance heater segments 16 begin at their connections 23 to the internal electrical resistance heater cable connector wires 22, a distance of about one tenth to one half the over-all length of flexible tube flow line 10 from warm blood/fluid inlet 12 and extending all the way to the outlet end of flexible tube flow line 10. Thus the length of each flexible elongated disposable internal electrical resistance heater segment (and the heated length of flexible tube flow line 10 is about one half to nine tenths the over-all length of flexible tube flow line 10. The flexible elongated electrical resistance heater segments 16 are preferably bare metal with a high temperature coefficient of resistance such as nickel or an alloy such as 70% Nickel, 30% Iron, but may also be made of electrically insulated

metal. Flexible elongated electrical resistance heater segments 16 are preferably in the form of flattened wires or ribbons about 0.0005 to 0.003 inch thick and about 0.10 to 0.30 inch wide. Round wires about 0.001 inch to 0.010 inch in diameter may also be used. Fig. 3 shows another form 26 of the internal electrical resistance heater segments 16 in which electrical resistance heater segments are made by winding the resistance wire in a tightly spaced helical form on elongated flexible insulator rods or tubes such as plastic about 0.1 inches in diameter, allowing a much longer wire with a much larger heat transfer area to be achieved. Fig. 4 shows yet another form 28 of the internal electrical resistance heater segments 16 made by winding the resistance wire in a tightly spaced quasi helical form on elongated flexible insulator strip shaped insulators such as plastic about 0.03 inch thick and about 0.10 to 0.25 inch wide, whereby a much longer length of wire and much larger heat transfer area may be achieved.

Electrical and Mechanical Connections

The internal electrical resistance heater segments 16 are electrically and mechanically connected, by means such as soldering or spot welding, to disposable internal electrical resistance heater cable connector wires 22 and to each other through disposable internal electrical resistance heater segment connector wire 24 at the distal end of the air insulated patient line forming a series resistance circuit. These connections are shown clearly in Figs. 1A and

1B. As shown in Fig. 1, heater cable 18 is then connected to a temperature controller in the blood warmer using disposable internal heater connector plug 20. Temperature control may be achieved using the internal electrical resistance heater segments 16 as a sensor when made of a metal with a high TCR (temperature coefficient of resistance) or by a separate sensor such as a thermistor. Separate sensor 30, if employed, is connected to a temperature controller in the blood warmer through temperature sensor cable 21 and internal heater connector plug 20.

PREFERRED EMBODIMENT -- OPERATION

In operation, warm blood or intravenous fluid enters warm blood/fluid inlet 12 after being warmed by passing through an in-line blood warmer apparatus. Blood then passes slowly through disposable air insulated ~~patient intravenous line~~ flexible tube flow line made of polyvinyl chloride or other resinous material 10 toward warm blood/fluid outlet 14 which is connected to the patient. The annular air space of ~~patient-line~~ disposable air insulated flexible tube flow line 10 passively insulates warm blood in the central lumen from the ambient cooler air,

but this effect alone is inadequate at very low flow rates (below about 15 milliliters per minute). Heaters The flexible elongated electrical resistance heater segments 16 are energized by a temperature controller as necessary to keep the annular air space at approximately 42 degrees C, by replacing heat lost to cooler ambient air from the outer surface of disposable air insulated tubing flexible tube flow line 10. The sensor used to measure the annular air space temperature is preferably the high TCR (temperature coefficient of resistance) flexible elongated electrical resistance heater segments 16 themselves. The temperature controller utilizes the resistance as a function of temperature of flexible elongated electrical resistance heater segments 16 to apply power when needed to maintain the annular air space at about 42 degrees C. Alternatively, temperature sensor 30, such as a thermistor, shown in Fig. 1B may be used to measure the annular air space temperature near warm blood/fluid outlet to patient connection 14. Intravenous fluid is thereby delivered at normothermic temperature to the patient even at extremely low flow rates, down to essentially zero milliliters per minute.